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FORM PTO-1449 U.S. DEPARTMENT OF COMMERCE (Modified) PATENT AND TRADEMARK OFFICE		ATTY. DOCKET NO. 40015630-0004	SERIAL NO. 09/481,207
INFORMATION DISCLOSURE STATEMENT BY APPLICANT		APPLICANT J. Phillips	
(Use several sheets if necessary) (37 CFR 1.98 (b))		FILING DATE January 11, 2000	GROUP 1625

## U.S. PATENT DOCUMENTS

EXAMINER INITIAL	PATENT NUMBER	ISSUE DATE	PATENTEE	CLASS	SUB CLASS	FILING DATE
9.5	1. 4 0 4 5 5 6 4	08/30/77	Berntsson, et al.			
	2. 4 1 8 2 7 6 6	01/08/80	Krasso, et al.			
	3. 4 2 5 5 4 3 1	03/10/81	Junggren, et al.			
	4. 4 3 3 7 2 5 7	06/29/82	Junggren, et al.			
	5. 4 4 7 2 4 0 9	09/18/84	Senn-Bilfinger			
	6. 4 5 4 4 7 5 0	10/01/85	Brandstrom, et al.			
	7. 4 6 2 0 0 0 8	10/28/86	Brandstrom, et al.			
	8. 4 6 3 6 4 9 9	01/13/87	Brandstrom, et al.			
	9. 4 7 2 5 6 9 1	02/16/88	Brandstrom, et al.			
	10. 4 7 3 8 9 7 4	04/19/88	Brandstrom, et al.			
	11. 4 7 8 6 5 0 5	11/22/88	Lovgren, et al.			
	12. 4 8 5 3 2 3 0	08/01/89	Lovgren, et al.			
	13. 5 0 0 8 2 7 8	04/16/91	Brandstrom, et al.			
	14. 5 0 1 3 7 4 3	05/07/91	Iwahi, et al.			
	15. 5 0 1 9 5 8 4	05/28/91	Brandstrom, et al.			
	16. 5 0 2 5 0 2 4	06/18/91	Brandstrom, et al.			
	17. 5 0 3 9 8 0 6	08/13/91	Brandstrom, et al.			
	18. 5 0 4 5 3 2 1	09/03/91	Makino, et al.			
	19. 5 0 7 5 3 2 3	12/24/91	Fain, et al.			
	20. 5 0 9 3 1 3 2	03/03/92	Makino, et al.			
	21. 5 0 9 3 3 4 2	03/03/92	Tomoi, et al.			
	22. 5 1 0 6 8 6 2	04/21/92	Briving, et al.			
	23. 5 2 1 5 9 7 4	06/01/93	Alminger, et al.			
	24. 5 2 1 9 8 7 0	06/15/93	Kim			
	25. 5 2 3 2 7 0 6	08/03/93	Coll			
	26. 5 3 7 4 7 3 0	12/20/94	Slemon, et al.			
	27. 5 3 8 5 7 3 9	01/31/95	Debregeas, et al.			
	28. 5 3 8 6 0 3 2	01/31/95	Brandstrom			
	29. 5 3 9 1 7 5 2	02/21/95	Hoerrner, et al.			
	30. 5 3 9 5 3 2 3	03/07/95	Berglund			
	31. 5 3 9 9 7 0 0	03/21/95	Min, et al.			
	32. 5 4 1 7 9 8 0	05/23/95	Goldman, et al.			
	33. 5 4 3 0 0 4 2	07/04/95	Lindberg, et al.			
	34. 5 4 4 7 9 2 3	09/05/95	Castrenich, et al.			
	25. 5 4 7 0 9 8 3	11/28/95	Slemon, et al.			
	36. 5 5 8 9 4 9 1	12/31/96	Nakanishi, et al.			
	37. 5 5 9 9 7 9 4	02/04/97	Eek, et al.			
	38. 5 6 2 9 3 0 5	05/13/97	Eek, et al.			
	39. 5 6 3 3 2 4 4	05/27/97	Eek, et al.			
	40. 5 6 9 0 9 6 0	11/25/97	Bengtsson, et al.			
9.5	41. 5 6 9 3 8 1 8	12/02/97	Von Unge			

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## U.S. PATENT DOCUMENTS

42.	5	7	1	4	5	0	4	02/03/98	Lindberg, et al.		
43.	5	7	1	4	5	0	5	02/03/98	Hasselkus		
44.	5	7	3	1	0	0	2	03/24/98	Olovson, et al.		
45.	5	7	5	3	2	6	5	05/19/98	Bergstrand, et al.		
46.	5	7	6	6	6	2	2	06/16/98	Nelson		
47.	5	7	7	6	7	6	5	07/07/98	Graham, et al.		
48.	5	8	1	4	3	3	8	09/29/98	Veronesi		
49.	5	8	1	7	3	3	8	10/06/98	Bergstrand, et al.		
50.	5	8	4	0	7	3	7	11/24/98	Phillips		
51.	5	8	7	7	1	9	2	03/02/99	Lindberg, et al.		
52.	5	8	8	3	1	0	2	03/16/99	Hamley, et al.		
53.	5	8	8	5	5	9	4	03/23/99	Nilsen, et al.		
54.	5	9	0	0	4	2	4	05/04/99	Kallstrom, et al.		
55.	5	9	2	9	2	4	4	07/27/99	Von Unge		
56.	5	9	3	9	0	9	1	08/17/99	Eoga, et al.		
57.	5	9	4	8	7	8	9	09/07/99	Larsson, et al.		
58.	5	9	5	5	1	0	7	09/21/99	Augello, et al.		
59.	5	9	5	8	9	5	5	09/28/99	Gustavsson, et al.		
60.	5	9	6	2	0	2	2	10/05/99	Bolt, et al.		
61.	5	9	6	5	1	6	2	10/12/99	Fuisz, et al.		
62.	5	9	7	9	5	1	5	11/09/99	Olsson		
63.	6	0	1	3	2	8	1	01/11/00	Lundberg, et al.		

## FOREIGN PATENT OR PUBLISHED FOREIGN PATENT APPLICATION

EXAMINER INITIAL	DOCUMENT NUMBER	PUBLIC- ATION DATE	COUNTRY OR PATENT OFFICE	CLASS	SUB CLASS	TRANS- LATION YES NO
64.	8 8 3 5 1	04/30/86	RO			
65.	2 1 8 9 6 9 8	11/04/87	UK			
66.	1 2 3 4 1 1 8	03/15/88	CA			
67.	0 5 1 9 4 2 2 5	08/03/93	JP/English Trans. Attached			
68.	9 4 0 0 1 1 2	01/06/94	WO			
69.	9 4 0 2 1 4 0	02/03/94	WO A1			
70.	9 5 3 2 9 5 7	12/07/95	WO A1			
71.	9 6 0 1 6 1 2	01/25/96	WO A1			
72.	9 6 0 1 6 2 2	01/25/96	WO A1			
73.	9 6 2 4 3 7 5	08/15/96	WO A1			
74.	9 7 2 5 0 3 0	07/17/97	WO A1			
75.	9 7 4 1 1 1 4	11/06/97	WO A1			
76.	9 7 4 8 3 8 0	12/24/97	WO A1			
77.	9 8 0 2 3 6 8	01/22/98	WO A1			
78.	9 8 2 8 2 9 4	07/02/98	WO A1			
79.	9 8 5 0 0 1 9	11/12/98	WO A1			

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80.		9	8	5	3	8	0	3	12/03/98	WO A1				
81.		9	8	5	4	1	7	1	12/03/98	WO A1				
82.		9	9	0	0	3	8	0	01/07/99	WO A1				
83.		9	9	0	8	5	0	0	02/25/99	WO A2				
84.		9	9	2	5	7	1	1	05/27/99	WO A1				
85.		9	9	2	7	9	1	7	06/10/99	WO A1				
86.		9	9	2	9	3	2	0	06/17/99	WO A1				
87.		9	9	2	9	2	9	9	06/17/99	WO A1				
88.	1	9	7	5	2	8	4	3	07/01/99	DK				
89.		9	9	3	2	0	9	1	07/01/99	WO A1				
90.		9	9	3	2	0	9	3	07/01/99	WO A1				
91.		0	0	2	6	1	8	5	05/11/00	WO A2 & A3				

## OTHER DOCUMENTS (Including Author, Title, Date, Place of Publication)

92.		"Agents for Control of Gastric Acidity and Treatment of Peptic Ulcers", Chapter 37, pp. 907-909, 1768.
93.		"Omeprazole, An Updated Review of its Pharmacology and Therapeutic Use in Acid-Related Disorders" by D. McTavish, et al., <u>Drugs</u> , Vol. 42, No. 1, pp. 138-170 (1991).
94.		"Omeprazole, Overview and Opinion" by S. Holt, et al., <u>Digestive Diseases and Sciences</u> , Vol. 36, No. 4, pp. 385-393 (April 1991).
95.		"Pantoprazole, A Review of its Pharmacological Properties and Therapeutic Use in Acid-Related Disorders" by A. Fitton, et al., <u>Drugs</u> , Vol. 51, No. 3, pp. 460-482 (March 1996).
96.		"Differential Stereoselective Pharmacokinetics of Pantoprazole, a Proton Pump Inhibitor in Extensive and Poor Metabolizers of Pantoprazole - A Preliminary Study" by M. Tanaka, et al., <u>Chirality</u> , Vol. 9, pp. 17-21 (1997).
97.		"A Prospective Study of Simplified Omeprazole Suspension for the Prophylaxis of Stress-related Mucosal Damage" by J. Phillips, et al., <u>Critical Care Medicine</u> , Vol. 24, No. 11, pp. 1793-1800 (1996).
98.		"A Prospective Study of Omeprazole Suspension to Prevent Clinically Significant Gastrointestinal Bleeding From Stress Ulcers in Mechanically Ventilated Trauma Patients" by M. Lasky, et al., <u>The Journal of Trauma: Injury Infection, and Critical Care</u> , Vol. 44, No. 3, pp. 527-533 (March 1998).
99.		"Effect of Combined Administration of Lansoprazole and Sofalcone on Microvascular and Connective Tissue Regeneration After Ethanol-induced Mucosal Damage" by M. Nakamura, et al., <u>Journal of Clinical Gastroenterology</u> , Vol. 27, Supp. 1, pp. 170-77 (1998).
100.		"The Effect of Omeprazole/Sodium Bicarbonate Solution Administration on the Accuracy of Subsequent pH Measurements Through the Nasogastric Tube" by J. Whipple, et al., <u>Critical Care Medicine</u> , Vol. 23, No. 1 Supplement, p. A69 [Date stamped in Howard University Library on January 13, 1995].

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## OTHER DOCUMENTS (Including Author, Title, Date, Place of Publication)

9.7	101.	"The Effect of Omeprazole/Sodium Bicarbonate Solution Administration on the Accuracy of Subsequent pH Measurements Through the Nasogastric Tube" by J. Whipple, et al., <u>Critical Care Medicine</u> , Vol. 23, No. 1 Supplement, p. A69 (January 1995). [Date stamped in Walter Reed Army Medical Center Medical Library on January 17, 1995].
	102.	"The Effect of Omeprazole/Sodium Bicarbonate Solution Administration on the Accuracy of Subsequent pH Measurements Through the Nasogastric Tube" by J. Whipple, et al., <u>Critical Care Medicine</u> , Vol. 23, No. 1 Supplement, p. A69 (January 1995). [Date stamped in FDA Medical Library January 6, 1995].
	103.	"The Effect of Omeprazole/Sodium Bicarbonate Solution Administration on the Accuracy of Subsequent pH Measurements Through the Nasogastric Tube" by J. Whipple, et al., <u>Critical Care Medicine</u> , Vol. 23, No. 1 Supplement, p. A69 (January 1995). [Date stamped in University of Illinois on January 10, 1995].
	104.	"The Effect of Omeprazole/Sodium Bicarbonate Solution Administration on the Accuracy of Subsequent pH Measurements Through the Nasogastric Tube" by J. Whipple, et al., <u>Critical Care Medicine</u> , Vol. 23, No. 1 Supplement, p. A69 (January 1995). [Date stamped in Central DuPage Hospital Medical Library on January 10, 1995].
	105.	"The Effect of Omeprazole/Sodium Bicarbonate Solution Administration on the Accuracy of Subsequent pH Measurements Through the Nasogastric Tube" by J. Whipple, et al., <u>Critical Care Medicine</u> , Vol. 23, No. 1 Supplement, p. A69 (January 1995). [Date stamped in University of Missouri Health Sciences Library January 6, 1995].
	106.	"The Effect of Omeprazole/Sodium Bicarbonate Solution Administration on the Accuracy of Subsequent pH Measurements Through the Nasogastric Tube" by J. Whipple, et al., <u>Critical Care Medicine</u> , Vol. 23, No. 1 Supplement, p. A69 (January 1995). [Although allegedly date stamped in St. Vincent's Hospital Medical Library on January 3, 1995, interviews of library personnel revealed that this Supplement was not received until Jan. 9, 1995, as the January 9, 1995 date is found in their computerized database.]
	107.	"Lansoprazole Capsules and Amoxicillin Oral Suspension in the Treatment of Peptic Ulcer Disease" by J. Hatlebakk, et al., <u>Scand. J. Gastroenterol.</u> , Vol. 30, No. 11, pp. 1053-57 (1995).
	108.	"Nicotinamide Pharmacokinetics in Humans: Effect of Gastric Acid Inhibition, Comparison of Rectal vs Oral Administration and the Use of Saliva for Drug Monitoring" by M.R. Stratford, et al. <u>J Cancer</u> , Vol. 74, No. 1, pp. 16-21 (July 1996).
	109.	"Comments of the Report of 'Association' of Omeprazole with DNA by Phillips, et al." by S.P. Adams <u>Mutagenesis</u> , Vol. 7, No. 5, pp. 395-396 (September 1992).
	110.	"Interaction of Omeprazole with DNA in Rat Issues" by D.H. Phillips, <u>Mutagenesis</u> , Vol. 7, No. 4, pp. 277-283 (July 1992).
	111.	"Stability of Omeprazole in an Extemporaneously Prepared Oral Liquid" by R.A. Quercia, et al., <u>American Journal of Health-System Pharmacy</u> , Vol. 54, pp. 1833-1836 (August 15, 1997).
	112.	"Simplified Omeprazole Solution For The Prophylaxis of Stress-Related Mucosal Damage In Critically Ill Patients", by J. Phillips, et al., <u>Critical Care Medicine</u> , Vol. 22, No. 1, p. A53 (January 1994).
✓	113.	"Effective Gastric Acid Suppression After Oral Administration of Enteric-Coated Omeprazole Granules" by M.A. Mohiuddin, et al., <u>Digestive Diseases and Sciences</u> , Vol. 42, No. 4, pp. 715-719 (April 1997).
9.7	114.	"Endoscopic Topical Therapy for the Treatment of Helicobacter Pylori Infection" by K. Kihira, et al. <u>J Gastroenterol</u> , Vol. 31, Suppl 9, pp. 66-68 (November 1996).
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## OTHER DOCUMENTS (Including Author, Title, Date, Place of Publication)

9.7	115.	"Pharmacokinetic Evaluation of Omeprazole Suspension Following Oral Administration in Rats: Effect of Neutralization of Gastric Acid" by K. Watanabe, et al., <u>Acta Med Okayama</u> , Vol. 50, No. 4, pp. 219-222 (August 1996).
	116.	"Pharmacokinetics of Lansoprazole in Hemodialysis Patients" by M. Karol, et al., <u>J Clin Pharmacol</u> , Vol. 35, pp. 815-820 (August 1995).
	117.	"Omeprazole: Pharmacokinetics and Metabolism in Man" by C. Cederberg, et al., <u>Scand. J. Gastroenterol.</u> , Vol. 24, Suppl. 166, pp. 33-40 (1989).
	118.	"Synthesis and Structure-Activity Relationships of Substituted 2-[2-imidazolylsulfinyl)methyl] Anilines As A New Class of Gastric H <sup>+</sup> /K <sup>+</sup> -ATPase Inhibitors. II." by T. Yamakawa, <u>Chem Pharm Bull (Tokyo)</u> , Vol. 40, No. 3, pp. 675-682 (March 1992).
	119.	"Studies on (H <sup>+</sup> )-K <sup>+</sup> -ATPase Inhibitors of Gastric Acid Secretion. Prodrugs of 2-[(2-Pyridinylmethyl)sulfinyl]benzimidazole Proton-Pump Inhibitors" by J. Sih, et al., <u>Journal of Medicinal Chemistry</u> , Vol. 34, No. 3, pp. 1049-1062 (March 1991).
	120.	"Effects of Pantoprazole, A Novel H <sup>+</sup> /K <sup>+</sup> -ATPase Inhibitor, On Duodenal Ulcerogenic and Healing Responses in Rats: A Comparative Study with Omeprazole and Lansoprazole" by Takeuchi, et al., <u>J. Gastroenterol. Hepatol.</u> , Vol. 14, No. 3, p. 251-57 (1999).
	121.	"Pharmacokinetics, Metabolism and Interactions of Acid Pump Inhibitors: Focus on Omeprazole, Lansoprazole and Pantoprazole" by T. Andersson, <u>Clin. Pharmacokinet.</u> , Vol. 31, No. 1, pp. 9-28 (July 1996).
	122.	"Nasogastric Administration of Omeprazole", <u>The Australian Journal of Hospital Pharmacy</u> , Vol. 28, No. 3, pp. 174-176 (1998).
	123.	"Bioavailability and Efficacy of Omeprazole Given Orally and By Nasogastric Tube" by C. Larson, et al., <u>Digestive Diseases and Sciences</u> , Vol. 41, No. 3, pp. 475-479 (March 1996).
	124.	"Nasogastric Omeprazole: Effects on Gastric pH in Critically Ill Patients" by D. Balaban, et al., <u>The American Journal of Gastroenterology</u> , Vol. 92, No. 1, pp. 79-83 (1997).
	125.	"Comparison of 24-hour Intragastric pH Using Four Liquid Formulations of Lansoprazole and Omeprazole" by V. Sharma, <u>American Journal of Health-System Pharmacists</u> , Vol. 56, Suppl 4, pp. S18-S21 (December 1, 1999).
	126.	"The Stability of Simplified Lansoprazole Suspension (SLS)" by J. Phillips, et al., <u>Gastroenterology</u> , Vol. 116, No. 4, pg. G0382 (April 1999).
	127.	"Effect on 24-hour Intragastric Acidity of Simplified Omeprazole Solution (SOS) Administered Via Gastrostomy", by V. Sharma, et al., <u>AJG</u> , Vol. 92, No. 9, p. 1625, Section 169 (1997).
	128.	"Simplified Lansoprazole Suspension (SLS): A Proton Pump Inhibitor (PPI) In A Liquid Formulation That Works" by V. Sharma, et al., <u>AJG</u> , p. 1647, Section 153 (September 1998).
	129.	"Simplified Lansoprazole Suspension - A Liquid Formulation of Lansoprazole - Effectively Suppresses Intragastric Acidity When Administered Through a Gastrostomy" by V. Sharma, et al., <u>The American Journal of Gastroenterology</u> , Vol. 94, No. 7, pp. 1813-1817 (July 1999).
9.7	130.	"The Effects on Intragastric Acidity of Per-Gastrostomy Administration of An Alkaline Suspension of Omeprazole" by V. Sharma, et al., <u>Aliment Pharmacol Ther</u> , Vol. 13, pp. 1091-1095 (1999).
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9.7	131.	"A Multicenter, Prospective, Randomized Clinical Trial of Continuous Infusion I.V. Ranitidine vs. Omeprazole Suspension in the Prophylaxis of Stress Ulcers" by J. Phillips, et al., <u>Critical Care Medicine</u> , Vol. 26, No. 1 (Suppl.), p. A101, No. 222 (1998).
	132.	"Gastrointestinal Drugs", <u>The American Medical Association Drug Evaluation</u> , Vol. 2, The American Medical Association, Chicago, 1:8 (Bennett & Dickson, eds.).
	133.	"Pharmacokinetics of [ <sup>14</sup> C]Omeprazole in Patients with Liver Cirrhosis" by T. Andersson, et al., <u>Clin Pharmacokinet.</u> , Vol. 24, No. 1, pp. 71-78 (1993).
	134.	"Pharmacokinetics and Bioavailability of Omeprazole After Single and Repeated Oral Administration in Healthy Subjects" by T. Andersson, et al., <u>Br. J. Clin. Pharmac.</u> , Vol. 29, pp. 557-563 (1990).
	135.	"Development of An Oral Formulation of Omeprazole" by A. Pilbrant, et al., <u>Scand. J. Gastroenterol.</u> , Vol. 20, (Suppl. 108) pp. 113-120 (1985).
	136.	"Pharmacokinetics of Various Single Intravenous and Oral Doses of Omeprazole" by T. Andersson, et al., <u>European Journal of Pharmacology</u> , Vol. 39, pp. 195-197 (1990).
	137.	"Pharmacokinetic Study of Omeprazole in Elderly Healthy Volunteers" by S. Landahl, et al., <u>Clin. Pharmacokinet.</u> , Vol. 23, No. 6, pp. 469-476 (1992).
	138.	"The Pharmacokinetics of Omeprazole in Humans - A Study of Single Intravenous and Oral Doses" by C. Regardh, et al., <u>Therapeutic Drug Monitoring</u> , Vol. 12, No. 2, pp. 163-172 (1990).
	139.	"Bolus or Intravenous Infusion of Rantidine: Effects on Gastric pH and Acid Secrecion" by Ballesteros, et al., <u>Ann. Intern. Med.</u> , Vol. 112, pp. 334, 339 (1990).
	140.	"Therapeutic Use of Omeprazole For Refractory Stress-Induced Gastric Mucosal Hemorrhage" by Barie & Hariri, <u>Critical Care Medicine</u> , Vol. 20, pp. 899-901 (1992).
	141.	"Let's Agree on Terminology: Definition of Sepsis" by Bone, <u>Critical Care Medicine</u> , Vol. 19, p. 27 (1991).
	142.	"Antacids vs. Sucralfate in Preventing Acute Gastrointestinal Tract Bleeding in Abdominal Aortic Surgery" by Borrero, et al., <u>Arch. Surg.</u> , Vol. 121, pp. 810-12 (1986).
	143.	<u>The Pharmacologic Basis of Therapeutics</u> by Brunton, p. 907 (1990).
	144.	"Central Nervous System Reactions to Histamine-2 Receptor Blockers" by Cantu & Korek, Vol. 114, pp. 1027-34 (1994).
	145.	"Comparison of Acid Neutralizing and Non-acid Neutralizing Stress Ulcer Prophylaxis in Thermally Injured Patients" by Cioffi, et al., Vol. 36, pp. 541-47 (1994).
	146.	"Risk Factors For Gastrointestinal Bleeding in Critically Ill Patients" by Cook, et al., Vol. 330, pp. 377-81 (1994).
	147.	"Stress Ulcer Prophylaxis in the Critically Ill: A Meta Analysis" by Cook, et al., Vol. 91, pp. 519-27 (1991).
	148.	"Nasocomial Pneumonia and the Role of Gastric pH: A Meta Analysis" by Cook, et al., Vol. 100, pp. 7-13 (1991).
✓	149.	"Acute Gastroduodenal Disease After Thermal Injury: An Endoscopic Evaluation of Incidence and Natural History" by Czaja, et al., Vol. 291, pp. 925-29 (1974).
9.7	150.	"Does pH Paper Accurately Reflect Gastric pH?" by Dobkin, et al., Vol. 18, pp. 985-88 (1990).

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151.	"Nosocomial Pneumonia in Intubated Patients Given Sucralfate As Compared With Antacids or Histamine Type 2 Blockers" by Driks et al., <u>N. Eng. J. Med.</u> , Vol. 317, pp. 1376-82 (1987).
152.	"Prospective Trial Comparing a Combination pH Probe-Nasogastric Tube With Aspirated Gastric pH" by Eisenberg, et al., <u>Critical Care Medicine</u> , Vol. 18, 1092-95 (1990).
153.	"Pneumonia and Stress Ulceration in Severely Injured Patients" by Fabian et al., Vol. 128, p. 1855 (1993).
154.	"Substituted Benzimidazoles Inhibit Gastric Acid Secretions by Blocking H <sup>+</sup> /K <sup>+</sup> -ATPase" by Fellenius, et al., <u>Nature</u> , Vol. 290, pp. 159-61 (1981).
155.	Predictive Value of Intramural pH and Other Risk Factors For Massive Bleeding From Stress Ulceration" by Fiddian-Green, et al., <u>Gastroenterology</u> , Vol. 8, pp. 613-20 (1983).
156.	"Function and Structure of Parietal Cells After H <sup>+</sup> /K <sup>+</sup> -ATPase Blockade" by Fryklund, et al., <u>Am. J. Physiol.</u> , Vol. 254, pp. G399-407 (1988).
157.	"Thrombocytopenia Associated with Hypersensitivity to Rantidine: Possible Cross-Reactivity" by Gafter, et al., Vol. 64, pp. 560-62 (1989).
158.	"CDC Definitions for Nosocomial Infections" by Garner, et al., <u>Am. J. Infect. Control</u> , Vol. 16, pp. 128-40 (1988).
159.	"Intragastric pH Measurement Using a Novel Disposable Sensor" by Heath, et al., <u>Intes. Care Med.</u> , Vol. 14, pp. 232-35 (1988).
160.	"Effect of Intravenous Infusion of Omeprazole and Rantidine on Twenty-Four-Hour Intragastric pH" by Kiilerich, et al., Vol. 56, pp. 25-30 (1995).
161.	"Prevention of Upper Gastrointestinal Bleeding in Long Term Ventilated Patients" by Laggner, et al., <u>Am. J. Med.</u> , Vol. 86, Suppl. 6A, pp. 81-84 (1989).
162.	"Gastric Response to Severe Head Injury" by Larson, et al., <u>Am. J. Surg.</u> , Vol. 147, pp. 97-105 (1984).
163.	"Pathogenesis, Diagnosis and Treatment of Acute Gastric Mucosa Lesions" by Marrone & Silen, <u>Clin. Gastroenterol.</u> , Vol. 13, pp. 635-50 (1984).
164.	"Continuous Intravenous Cimetidine Decreases Stress-Related Upper Gastrointestinal Hemorrhage" by Martin, et al., <u>Critical Care Medicine</u> , Vol. 21, pp. 19-39 (1993).
165.	"Evaluation of Various Techniques to Monitor Intragastric pH" by Meiners et al., <u>Arch. Surg.</u> , Vol. 117, pp. 288-91 (1982).
166.	"Electrolyte and Acid-base Disorders" by Oh & Carroll, <u>The Pharmacologic Approach to the Critically Ill Patient</u> , pp. 966-67 (Chernow, B. ed. 1994).
167.	"Control of Gastric pH With Cimetidine Boluses Versus Primed Infusions" by Ostro et al., <u>Gastroenterology</u> , Vol. 89, pp. 532-37 (1985).
168.	"Cimetidine for Prevention and Treatment of Gastroduodenal Mucosal Lesions in Patients" by Peura & Johnson, <u>Ann. Intern. Med.</u> , Vol. 103, pp. 173-177 (1985).
169.	"Occurrence of Nasocomial Pneumonia in Mechanically Ventilated Trauma Patients" by Pickworth, et al., <u>Critical Care Medicine</u> , Vol. 12, pp. 1856-62 (1993).
170.	"Methods of Prophylaxis in Stress Ulcer Disease" by Priebe & Skillman, <u>World J. Surg.</u> , Vol. 5, pp. 223-33 (1981).

EXAMINER

Jane T. Fan

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FORM PTO-1449 U.S. DEPARTMENT OF COMMERCE (Modified) PATENT AND TRADEMARK OFFICE		ATTY. DOCKET NO. 40015630-0004	SERIAL NO. 09/481,207
INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Use several sheets if necessary) (37 CFR 1.98 (b))		APPLICANT J. Phillips	
		FILING DATE January 11, 2000	GROUP 1625

## OTHER DOCUMENTS (Including Author, Title, Date, Place of Publication)

J.T.	171.	"Nasocomial Pneumonia During Stress Ulcer Prophylaxis With Cimetidine and Sucralfate" by Ryan, et al., <u>Arch. Surg.</u> , Vol. 128, pp. 1353-57 (1993).
	172.	"Clinically Important Adverse Effects and Drug Interactions With H <sub>2</sub> -receptor Antagonists: An Update" by Sax, <u>Pharmacotherapy</u> , Vol. 7, pp. 110S-115S (1987).
	173.	"Stress Ulcer Prophylaxis: Still a Valid Option in the 1990s?" by Schepp, Vol. 54, pp. 189-99 (1993).
	174.	"Prophylactic Therapy for Acute Ulcer Bleeding: A Reappraisal" by Schuman, et al., <u>Ann. Intern. Med.</u> , Vol. 106, pp. 562-67 (1987).
	175.	"Stress Ulcer Prophylaxis: In Whom? With What?" by Schuster, <u>Critical Care Medicine</u> , Vol. 21, pp. 4-6 (1993).
	176.	"A Dosage Alternative for H-2 Receptor Antagonists, Continuous-Infusion" by Siepler, <u>Clin. Ther.</u> , Vol. 8, pp. 24-33 (1986).
	177.	"Role of Gastric Colonization in the Development of Pneumonia in Critically Ill Trauma Patients" by Simms, et al., <u>J. Trauma</u> , Vol. 31, pp. 531-36 (1991).
	178.	"Respiratory Failure, Hypotension, Sepsis and Jaundice: A Clinical Syndrome Associated With Lethal..." by Skillman, et al., <u>Am. J. Surg.</u> , Vol. 117, pp. 523-30 (1969).
	179.	"The Gastric Mucosal Barrier: Clinical and Experimental Studies In Critically Ill and Normal Man..." by Skillman, et al., <u>Ann. Surg.</u> , Vol. 172, pp. 564-84 (1970).
	180.	"Changing Perspectives of Stress Gastritis Prophylaxis" by Smythe & Zarowitz, <u>Ann. Pharmacother.</u> , Vol. 28, pp. 1073-84 (1994).
	181.	"Thrombocytopenia Associated With Rantidine" by Spychal & Wickman, <u>Br. Med. J.</u> , Vol. 291, p. 1687 (1985).
	182.	"Stress Ulcer Prophylaxis - Quo Vadis?" by Tryba, <u>Intens. Care Med.</u> , Vol. 20, pp. 311-13 (1994).
	183.	"Risk of Acute Stress Bleeding and Nosocomial Pneumonia in Ventilated Intensive Care Patients. Sucralfate vs. Antacids" by Tryba, <u>Am. J. Med.</u> , Vol. 87 (3B) 117-24 (1987).
	184.	"Side Effects of Ranitidine" by Vial, et al., <u>Drug Saf.</u> , Vol. 6, pp. 94-117 (1991).
	185.	"The Relationship Between Gastric Acid Secretion and Gastric H <sup>+</sup> /K <sup>+</sup> -ATPase Activity" by Wallmark, et al., <u>J. Biol. Chem.</u> , Vol. 260, pp. 13681-84 (1985).
	186.	"Tolerance During Dosing with H <sub>2</sub> Receptor Antagonists: An Overview" by Wilder-Smith & Merki, <u>Scand. J. Gastroenterol.</u> , Vol. 27, Suppl. 193, pp. 14-19 (1992).
	187.	"The Prevention of Gastro-Intestinal Tract Bleeding in Patients in an Intensive Care Unit" by Zinner, et al., <u>Surg. Gynecol. Obstet.</u> , Vol. 153, pp. 214-20 (1981).
	188.	"Influence of Insulin Antibodies on Pharmacokinetics and Bioavailability of Recombinant Human..." by Gray, et al., <u>British Med. J.</u> , Vol. 290, pp. 1687-90 (1985).
	189.	"Nasogastric Administration of Omeprazole for Control of Gastric pH" by M. Carroll, et al., <u>10<sup>th</sup> World Congresses of Gastroenterology</u> , Abstracts (October 2-7, 1994).
J.T.	190.	"A Lansoprazole Suspension Formulation As An Alternative to Capsules for Oral Administration" by S. Lockhart, et al., <u>World Congresses of Gastroenterology</u> , Abstract Exh A2074 (September 6-11, 1998).
EXAMINER Jane T. Fan		DATE CONSIDERED 8/28/01
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	FILING DATE January 11, 2000	

## OTHER DOCUMENTS (Including Author, Title, Date, Place of Publication)

9.7	191.	"Gastric Acid Antisecretory Effect of Two Different Dosage Forms of Omeprazole During Prolonged Oral Treatment in the Gastric Fistula Dog" by Larsson, et al., Vol. 23, No. 8, pp. 1013-19 (1988).
	192.	"Effect of Various Salts on the Stability of Lansoprazole, Omeprazole, and Pantoprazole as Determined by High-Performance Liquid Chromatography" by A. Ekpe, et al., <u>Drug Development and Industrial Pharmacy</u> , Vol. 25, No. 9, pp. 1057-1065 (1999).
	193.	"Inhibition of Gastric Secretion by Omeprazole and Efficacy of Calcium Carbonate in the Control of Hyperphosphatemia in Patients on Maintenance Hemodialysis" by Sechet, et al., <u>Nephrologie</u> , Vol. 20, No. 4, pp. 213-16 (1999).
	194.	"Role of the Time of Administration of Calcium Carbonate in the Control of Hyperphosphatemia in Patients on Maintenance Hemodialysis" by Sechet, et al., <u>Nephrologie</u> , Vol. 20, No. 4, pp. 209-12 (1999).
	195.	Onset of Action of Antisecretory Drugs: Beneficial Effects of a Rapid Increase in Intragastric pH in Acid Reflux Disease" by Pipkin, et al, <u>Scand. J. Gastroenterol. Supp.</u> , Vol. 230, pp. 3-8 (1999).
	196.	"Omeprazole Disposition in Humans" by Regardh, et al., <u>Ther. Drug Monit.</u> , Vol. 12, No. 2, pp. 165 (1990).
	197.	"Evaluation of Buffering Capacity and Acid Neutralizing pH Time Profile of Antacids" by M. Lin, et al., <u>J Formos Med Assoc</u> , Vol. 97, No. 10, pp. 704-710 (1998).
	198.	"A Study of Antacid Buffers: I. The Time Factor in Neutralization of Gastric Acidity", by J. Holbert, et al., <u>Journal of The American Pharmaceutical Association (Scientific Edition)</u> , Vol. 36, pp. 149-151 (1947).
	199.	"Buffered and Isotonic Solutions", <u>Physical Pharmacy</u> , Chapter 8, pp. 169-189.
	200.	"Influence of Insulin Antibodies on Pharmacokinetics and Bioavailability of Recombinant Human..." by Gray, et al., <u>British Medical Journal</u> , 290: 1687-1690 (1985).
	201.	"Inhibition of Basal and Betazole - and Sham-Feeding-Induced Acid Secretion by Omeprazole in Man" by Lind, et al., <u>Scand. J. Gastroenterol</u> , 21:1004-1010 (1986).
	202.	"Lansoprazole: Phase I Study of Lansoprazole (AG-1749) Antiulcer Agent (Tablet Form)" by A. Nakagawa, et al., pp. 33-34 (1991).
	203.	"Pantoprazole Bicarbonate Suspension (PBS) Provides Oral Bioavailability Comparable To Tablet" by J. Paul, et al., <u>Critical Care Medicine</u> , (Feb. 2001).
	204.	<u>Physical Pharmacy - Physical Chemicals Principles in the Pharmaceutical Sciences</u> , Fourth Edition, by A. Martin, et al. (1993).
	205.	"Journal of Clinical Therapeutics & Medicines" by Nakagawaa, et al., Vol. 7, No. 1, pp. 33-50 (1191).
	206.	Organic Chemistry by Wade, Pritice-Hall, Inc., p. 349 (1987).
9.7	207.	"The Effect of Omeprazole/Sodium Bicarbonate Solution Administration on the Accuracy of Subsequent pH Measurements Through the Nasogastric Tube" by J. Whipple, et al., Vol. 28, No. 1 (Suppl), p. A69 (January 1995).

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INFORMATION DISCLOSURE STATEMENT BY APPLICANT	APPLICANT J. Phillips		
(Use several sheets if necessary) (37 CFR 1.98 (b))	FILING DATE January 11, 2000	GROUP 1625	

## OTHER DOCUMENTS (Including Author, Title, Date, Place of Publication)

208.	"High Acid Buffering Capacity of Protein Hydrolysate Infant Formulas" by I. Korponay-Szabo, et al., <u>Journal of Pediatric Gastroenterology and Nutrition</u> , Vol. 31, Supplement 2, Abstract 956 (August 5-9, 2000).
209.	"Esomeprazole" by C. Spencer, et al., <u>Drugs</u> 2000, Vol. 60, No. 2, pp. 321-329 (August 2000).
210.	"Zollinger-Ellison Syndrome - Clinical Presentation in 261 Patients" by P. Roy, et al., <u>Medicine</u> , Vol. 79, No. 6, pp. 379-411 (2000).
211.	"Overuse of Proton Pump Inhibitors" by M. Naunton, et al., <u>Journal of Clinical Pharmacy and Therapeutics</u> , Vol. 25, pp. 333-340 (2000).
212.	"The Proton-Pump Inhibitors: Similarities and Differences" by J. Horn, <u>Clinical Therapeutics</u> , Vol. 22, No. 3, pp. 266-280 (2000).
213.	"Pantoprazole: A New Proton Pump Inhibitor" by P. Jungnickel, <u>Clinical Therapeutics</u> , Vol. 22, No. 11, pp. 1268-1293 (2000).
214.	"Rabeprazole for the Prevention of Pathologic and Symptomatic Relapse of Erosive or Ulcerative Gastroesophageal Reflux Disease" by A. Caos, et al., <u>The American Journal of Gastroenterology</u> , Vol. 95, No. 11, pp. 3081-3088 (2000).
215.	"The Stability of Simplified Omeprazole Suspension (SOS)" by J. Phillips, et al., <u>Critical Care Medicine</u> , Vol. 26, No. 1 (Suppl.), pg. A101, No. 221 (1998).
216.	"A Multicenter Prospective, Randomized Clinical Trial of Continuous Infusion I.V. Ranitidine vs. Omeprazole Suspension in The Prophylaxis of Stress Ulcers" by J. Phillips, et al., <u>Critical Care Medicine</u> , Vol. 26, No. 1 (Suppl.), pg. A101, No. 222 (1998).
217.	(Deleted)

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INFORMATION DISCLOSURE STATEMENT BY APPLICANT	APPLICANT J. Phillips	
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## U.S. PATENT DOCUMENTS

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## FOREIGN PATENT OR PUBLISHED FOREIGN PATENT APPLICATION

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EXAMINER INITIAL	DOCUMENT NUMBER									PUBLIC- ATION  DATE	COUNTRY OR  PATENT OFFICE	CLASS	SUB  CLASS	TRANS- LATION	
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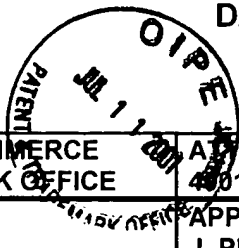
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	327.	0 0 2 8 9 7 5	05/25/00	WO A2 & A3			
	328.	0 0 3 0 6 1 2	06/02/00	WO A1			
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93	333.	0 0 7 8 2 9 3	12/28/00	WO A1			
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## Form PTO - 1449 (Modified)

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## U.S. PATENT DOCUMENTS

2-3	5	7	1	4	5	0	5	02/03/98	Hasselkus		
	5	7	3	1	0	0	2	03/24/98	Olovson		
	5	7	5	3	2	6	5	05/19/98	Bergstrand		
	5	7	6	6	6	2	2	09/05/95	Nelson		
	5	7	7	6	7	6	5	07/07/98	Graham, et al.		
	5	8	1	4	3	3	8	0929098	Veronesi		
	5	8	1	7	3	3	8	10/06/98	Bergstrand		
	5	8	4	0	7	3	7	11/24/98	Phillips		
	5	8	7	7	1	9	2	03/02/99	Lindberg, et al.		
	5	8	8	3	1	0	2	03/16/99	Hamley, et al.		
	5	8	8	5	5	9	4	03/23/99	Nilsen, et al.		
	5	9	0	0	4	2	4	05/04/99	Kallstrom		
	5	9	2	9	2	4	4	0727/99	Von Unge		
	5	9	3	9	0	9	1	08/17/99	Eoga, et al.		
	5	9	4	8	7	8	9	09/07/99	Larsson		
	5	9	5	5	1	0	7	09/21/99	Augello, et al.		
	5	9	5	8	9	5	5	09/28/99	Gustavsson		
	5	9	6	2	0	2	2	10/05/99	Bolt, et al.		
	5	9	6	5	1	6	2	10/12/99	Fuisz, et al.		
	5	9	7	9	5	1	5	11/09/99	Olsson		
9-3	6	0	1	3	2	8	1	01/11/00	Lundberg		

## FOREIGN PATENT OR PUBLISHED FOREIGN PATENT APPLICATION

	DOCUMENT NUMBER	PUBLICATION DATE	COUNTRY OR PATENT OFFICE	CLASS	SUB CLASS	TRANSLATION	
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2-3	8 8 3 5 1	30.04.86	RO				
	2 1 8 9 6 9 8	04.11.87	UK				
	1 2 3 4 1 1 8	03.15.88	CA				
0	5 1 9 4 2 2 5	03.08.93	JP				
	9 4 0 0 1 1 2	06.01.94	WO				
	9 4 0 2 1 4 0	03.02.94	WO				
	9 5 3 2 9 5 7	07.12.95	WO				
	9 6 0 1 6 1 2	25.01.96	WO				
	9 6 9 1 6 2 2	25.01.96	WO				
	9 6 2 4 3 7 5	15.08.96	WO				
	9 7 2 5 0 3 0	17.07.97	WO				
	9 7 4 1 1 1 4	06.11.97	WO				
	9 7 4 8 3 8 0	24.12.97	WO				
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#10  
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## U.S. PATENT DOCUMENTS

EXAMINER INITIAL	PATENT NUMBER							ISSUE DATE	PATENTEE	CLASS	SUB CLASS	FILING DATE
	4	0	4	5	5	6	4	08/30/77	Berntsson, et al.			
	4	1	8	2	7	6	6	09/11/78	Krasso, et al.			
	4	2	5	5	4	3	1	04/05/79	Junggren, et al.			
	4	3	3	7	2	5	7	06/29/82	Junggren, et al.			
	4	4	7	2	4	0	9	10/29/82	Senn-Bilfinger			
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SHEET 3\_ of 9\_

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		9	9	3	2	0	9	3	01.07.99	WO				
		0	0	2	6	1	8	5	11.05.00	WO				

## OTHER DOCUMENTS (Including Author, Title, Date, Place of Publication)

		"Agents for Control of Gastric Acidity and Treatment of Peptic Ulcers", Chapter 37, pp. 907-909.
		"An Updated Review of its Pharmacology and Therapeutic Use in Acid-Related Disorders" by D. McTavish, et. al., <u>Drugs</u> , Vol. 41, No. 1, pp. 138-170 (1991).
		"Omeprazole, Overview and Opinion" by S. Holt and C.W. Howden, <u>Digestive Diseases and Sciences</u> , Vol. 36, No. 4, pp. 385-393 (April 1991).
		"Pantoprazole, A Review of its Pharmacological Properties and Therapeutic Use in Acid-Related Disorders" by A. Fitton and L. Wiseman, <u>Drugs</u> , Vol. 51, No. 3, pp. 460-482 (March 1996).
		"Differential Stereoselective Pharmacokinetics of Pantoprazole, a Proton Pump Inhibitor in Extensive and Poor Metabolizers of Pantoprazole - A Preliminary Study" by M. Tanaka, et. al. <u>Chirality</u> , Vol. 9, pp. 17-21 (1997).
		"A prospective study of simplified omeprazole suspension for the prophylaxis of stress-related mucosal damage" by Phillips, et. al., <u>Crit Care Med</u> , Vol. 24, No. 11, pp. 1793-1800 (1996).
		"A prospective study of omeprazole suspension to prevent clinically significant gastrointestinal bleeding from stress ulcers in mechanically ventilated trauma patients" by M. Lasky, <u>The Journal of Trauma: Injury Infection, and Critical Care</u> , Vol. 44, No. 3, pp. 527-533 (1998).
		"Effect of combined administration of lansoprazole and sofalcone on microvascular and connective tissue regeration after ethanol-induced mucosal damage" by Nakamura M, et. al., <u>J. Clin. Gastroenterol.</u> , Vol. 27, Supp. 1, pp. 170-77 (1998).
		"The Effect of Omeprazole/Sodium Bicarbonate Solution Administration on the Accuracy of Subsequent pH Measurements Through the Nasogastric Tube" by J. Phillips, <u>Crit Care Med</u> , Vol. 23, No. 1 Supplement [Date stamped in Howard University Library on January 13, 1995].

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## OTHER DOCUMENTS (Including Author, Title, Date, Place of Publication)

		"The Effect of Omeprazole/Sodium Bicarbonate Solution Administration on the Accuracy of Subsequent pH Measurements Through the Nasogastric Tube" by J. Phillips, <u>Crit Care Med</u> , Vol. 23, No. 1 Supplement [Date stamped in Walter Reed Army Medical Center Medical Library on January 17, 1995].
		"The Effect of Omeprazole/Sodium Bicarbonate Solution Administration on the Accuracy of Subsequent pH Measurements Through the Nasogastric Tube" by J. Phillips, <u>Crit Care Med</u> , Vol. 23, No. 1 Supplement (Jan 1995) [Date stamped in FDA Medical Library January 6, 1995].
		"The Effect of Omeprazole/Sodium Bicarbonate Solution Administration on the Accuracy of Subsequent pH Measurements Through the Nasogastric Tube" by J. Phillips, <u>Crit Care Med</u> , Vol. 23, No. 1 Supplement (Jan 1995) [Date stamped in University of Illinois on January 10, 1995].
		"The Effect of Omeprazole/Sodium Bicarbonate Solution Administration on the Accuracy of Subsequent pH Measurements Through the Nasogastric Tube" by J. Phillips, <u>Crit Care Med</u> , Vol. 23, No. 1 Supplement (Jan 1995) [Date stamped in Central DuPage Hospital Medical Library on January 10, 1995].
		"The Effect of Omeprazole/Sodium Bicarbonate Solution Administration on the Accuracy of Subsequent pH Measurements Through the Nasogastric Tube" by J. Phillips, <u>Crit Care Med</u> , Vol. 23, No. 1 Supplement (Jan 1995) [Date stamped in University of Missouri Health Sciences Library January 6, 1995].
		"The Effect of Omeprazole/Sodium Bicarbonate Solution Administration on the Accuracy of Subsequent pH Measurements Through the Nasogastric Tube" by J. Phillips, <u>Crit Care Med</u> , Vol. 23, No. 1 Supplement (Jan. 1995). [Although allegedly date stamped in St. Vincent's Hospital Medical Library on January 3, 1995, interviews of library personnel revealed that this Supplement was not received until Jan. 9, 1995, as the January 9, 1995 date is found in their computerized database.]
		"Lansoprazole capsules and amoxicillin oral suspension in the treatment of peptic ulcer disease" by Hatlebakk JG, et. al., <u>Scand. J. Gastroenterol.</u> , Vol. 30, No. 11, pp. 1053-57 (1995).
		"Nicotinamide pharmacokinetics in humans: effect of gastric acid inhibition, comparison of rectal vs oral administration and the use of saliva for drug monitoring" by M.R. Stratford, et. al. <u>J Cancer</u> , Vol. 74, No. 1, pp. 16-21 (July 1996).
		"Comments of the report of 'association' of omeprazole with DNA by Phillips, et. al." by S.P. Adams <u>Mutagenesis</u> , Vol. 7, No. 5, pp. 395-396 (September 1992).
		"Interaction of omeprazole with DNA in rat tissues" by D.H. Phillips <u>Mutagenesis</u> , Vol. 7, No. 4, pp. 277-283 (July 1992).
		"Stability of omeprazole in an extemporaneously prepared oral liquid" by R.A. Quercia, et. al. <u>Am J Health Syst Pharm</u> , Vol. 54, No. 16, pp. 1833-1836 (August 15, 1997).
		"Simplified omeprazole solution for the prophylaxis of stress - related mucosal damage", <u>Crit Care Med</u> , 22: A53 (1994).
		"Effective gastric acid suppression after oral administration of enteric-coated omeprazole granules" by M.A. Mohiuddin, et. al. <u>Dig Dis Sci</u> , Vol. 42, No. 4, pp. 715-719 (April 1997).
		"Endoscopic topical therapy for the treatment of Helicobacter pylori infection" by K. Kihira, et. al. <u>J Gastroenterol</u> , Vol. 31, Suppl 9, pp. 66-68 (November 1996).

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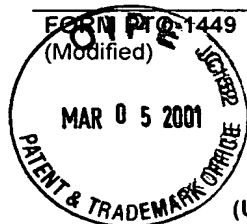
		"Pharmacokinetic evaluation of omeprazole suspension following oral administration in rats: effect of neutralization of gastric acid" by K. watanabe, et. al. <u>Acta Med Okayama</u> , Vol. 50, No. 4, pp. 219-222 (August 1996).
		"Pharmacokinetics of lansoprazole in hemodialysis patients" by M.D. Karol <u>J Clin Pharmacol</u> , Vol. 35, No. 8, pp. 815-820 (August 1995).
		"Omeprazole: pharmacokinetics and metabolism in man" by Cederberg C, et. al., <u>Scand. J. Gastroenterol.</u> , Vol. 166, Suppl. pp. 33-40 (1989).
		"Synthesis and structure-activity relationships of substituted 2-[2-imidazolylsulfinyl)methyl] anilines as a new class of gastric H <sup>+</sup> /K <sup>+</sup> -ATPase inhibitors. II." by T. Yamakawa <u>Chem Pharm Bull</u> (Tokyo), Vol. 40, No. 3, pp. 675-682 (March 1992)
		"Studies on (H <sup>+</sup> )-K <sup>+</sup> -ATPase inhibitors of gastric acid secretion. Prodrugs of 2-[(2-pyridinylmethyl)sulfinyl] benzimidazole proton-pump inhibitors" by J.C. Sih, et. al., <u>J Med Chem</u> , Vol. 34, No. 3, p. 1049-1062 (March 1991).
		"Effects of pantoprazole, a novel H <sup>+</sup> /K <sup>+</sup> -ATPase inhibitor, on duodenal ulcerogenic and healing responses in rats: a comparative study with omeprazole and lansoprazole" by Takeuchi et. al., <u>J. Gastroenterol. Hepatol.</u> , Vol. 14, No. 3, p. 251-57 (1999).
		"Pharmacokinetics, Metabolism and Interactions of Acid Pump Inhibitors: Focus on Omeprazole, Lansoprazole and Pantoprazole" by Andersson, <u>Clin. Pharmacokinet.</u> , Vol. 31, No. 1, pp. 9-28 (1996).
		"Nasogastric Administration of Omeprazole" <u>The Australian Journal of Hospital Pharmacy</u> , Vol. 28, No. 3 (1998).
		"Bioavailability and efficacy of omeprazole given orally and by nasogastric tube" by C. Larson, M.D., et. al., <u>Digestive Diseases and Sciences</u> , Vol. 41, No. 3, pp. 475-479 (March 1996).
		"Nasogastric Omeprazole: Effects on Gastric pH in Critically Ill Patients" by D. Balaban, et. al., <u>Am J of Gastroenterolgy</u> , Vol. 92, No. 1, pp. 79-83 (1997).
		"Comparison of 24-hour intragastric pH using four liquid formulations of lansoprazole and omeprazole" by V. Sharma, <u>Am J Health-Syst Pharm</u> , Vol. 56, Suppl 4, pp. S18-S21, (December 1, 1999).
		"The stability of simplified lansoprazole suspension (SLS)" by J.O. Phillips, <u>Gastroenterology</u> , Vol. 116, No. 4, pp. G0382.
		"Effect on 24-hour intragastric acidity of simplified omeprazole solution (SOS) administered via gastrostomy", by V. Sharma, <u>AJG</u> , Vol. 92, No. 9, pp. 169 (1997).
		"Simplified Lansoprazole Suspension (SLS): A Proton Pump Inhibitor (PPI) in a Liquid Formulation that Works" by V. Sharma, <u>AJG</u> , pp. 1647 (September 1998).
		"Simplified Lansoprazole Suspension - A Liquid Formulation of Lansoprazole - Effectively Suppress Intragastric Acidity When Administered Through a Gastrostomy" by V. Sharma, et. al., <u>AJG</u> , Vol. 94, No. 7, pp. 1813-1817 (1999).
		"The effects on intragastric acidity of per-gastrostomy administration of an alkaline suspension of omeprazole" by V. Sharma, et. al., <u>Aliment Pharmacol Ther</u> , Vol. 13, pp. 1091-1095 (1999).

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## OTHER DOCUMENTS (Including Author, Title, Date, Place of Publication)

		"A multicenter, prospective, randomized clinical trial of continuous infusion I.V. ranitidine vs. omeprazole suspension in the prophylaxis of stress ulcers" by J.O. Phillips, et. al., <u>Cri Care Med</u> , Vol. 26, No. 1 (Suppl.), pp. 222 (1998).
	*	"Gastrointestinal Drugs", <u>The American Medical Association Drug Evaluation</u> , Vol. 2, The American Medical Association, Chicago, 1:8 (Bennett & Dickson, eds.)
	*	"Pharmacokinetics of [ <sup>14</sup> C]Omeprazole in Patients with Liver Cirrhosis" by T. Andersson, <u>Clin Pharmacokinet</u> , Vol. No. 1, pp. 71-78 (1993)
	*	"Pharmacokinetics and bioavailability of omeprazole after single and repeated oral administration in healthy subjects" by T. Andersson, et al., <u>J. Clin. Pharmacol.</u> , Vol. 28, No. 5, pp. 557-563 (May 1990).
	*	"Development of an oral formulation of omeprazole" by A. Philbrant, <u>Scand. J. Gastroenterol. Suppl.</u> , Vol. 108, pp. 113-120 (1985).
	*	"Pharmacokinetics of various single intravenous and oral doses of omeprazole" by T. Andersson, et al., <u>Eur. J. Pharmacol.</u> , Vol. 39, pp. 195-197 (1990).
	*	"Pharmacokinetic Study of Omeprazole in Elderly Healthy Volunteers" by S. Landahl, <u>Clin. Pharmacokinet</u> , Vol. 23, No. 6, pp. 469-476 (1992).
	*	"The pharmacokinetics of omeprazole in humans - a study of single intravenous and oral doses" by C.G. Regardh, <u>Ther. Drug Monit.</u> , Vol. 12, No. 2, pp. 163-172 (March 1990).
	*	"Bolus or intravenous infusion of ranitidine: effects on gastric pH and acid secretion" by Ballesteros, et al., <u>Ann. Intern. Med.</u> , Vol. 112, pp. 334,39 (1990).
	*	"Therapeutic use of omeprazole for refractory stress-induced gastric mucosal hemorrhage" by Barie & Hariri, <u>Crit. Care Med.</u> , Vol. 20, pp. 899-901 (1992).
	*	"Let's agree on terminology: definition of sepsis" by Bone, <u>Crit. Care Med.</u> , Vol. 19, p. 27 (1991).
	*	"Antacids vs. sucralfate in preventing acute gastrointestinal tract bleeding in abdominal aortic surgery" by Borrero, et al., <u>Arch. Surg.</u> , Vol. 121, pp. 810-12 (1986).
	*	<u>The Pharmacologic Basis of Therapeutics</u> by Brunton, p. 907 (1990).
	*	"Central nervous system reactions to histamine-2 receptor blockers" by Cantu & Korek, Vol. 114, pp. 1027-34 (1994).
	*	"Comparison of acid neutralizing and non-acid neutralizing stress ulcer prophylaxis in thermally injured patients" by Cioffi, et al., Vol. 36, pp. 541-47 (1994).
	*	"Risk factors for gastrointestinal bleeding in critically ill patients" by Cook, et al., Vol. 330, pp. 377-81 (1994).
	*	"Stress ulcer prophylaxis in the critically ill: a meta analysis" by Cook et al., Vol. 91, pp. 519-27 (1991).
	*	"Nasocomial pneumonia and the role of gastric pH: a meta analysis" by Cook, et al., Vol. 100, p. 7-13 (1991).
	*	"Acute gastroduodenal disease after thermal injury: an endoscopic evaluation of incidence and natural history" by Czaja, et al., Vol. 291, pp. 925-29 (1974).
	*	"Does pH paper accurately reflect gastric pH?" by Dobkin et al., Vol. 18, pp. 985-88 (1990)

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## OTHER DOCUMENTS (Including Author, Title, Date, Place of Publication)

	*	"Nosocomial pneumonia in intubated patients given sucralfate as compared with antacids or histamine type 2 blockers" by Driks et al., <u>N. Eng. J. Med.</u> , Vol. 317, pp. 1376-82 (1987).
	*	"Prospective trial comparing a combination pH probe-Nasogastric tube with Aspirated gastric pH" by Eisenberg, et al., <u>Crit. Care Med.</u> , Vol. 18, 1092-95 (1990).
	*	"Pneumonia and stress ulceration in severely injured patients" by Fabian et al., Vol. 128, p. 1855 (1993).
	*	"Substituted benzimidazoles inhibit gastric acid secretions by blocking H <sup>+</sup> /K <sup>+</sup> -ATPase" by Fellenius, et al., <u>Nature</u> , Vol. 290, pp. 159-61 (1981).
	*	Predictive value of intramural pH and other risk factors for massive bleeding from stress ulceration" by Fiddian-Green, et al., <u>Gastroenterology</u> , Vol. 8, pp. 613-20 (1983).
	*	"Function and structure of parietal cells after H <sup>+</sup> /K <sup>+</sup> -ATPase blockade" by Fryklund et al., <u>Am. J. Physiol.</u> , Vol. 254, pp. G399-407 (1988).
	*	"Thrombocytopenia associated with hypersensitivity to rantidine: possible cross-reactivity" by Gafter et al., Vol. 64, pp. 560-62 (1989)
	*	"CDC definitions for nosocomial infections" by Garner et al., <u>Am. J. Infect. Control</u> , Vol. 16, pp. 128-40 (1988).
	*	"Intragastric pH measurement using a novel disposable sensor" by Heath et al., <u>Intes. Care Med.</u> , Vol. 14, pp. 232-35 (1988).
	*	"Effect of intravenous infusion of omeprazole and rantidine on twenty-four-hour intragastric pH" by Kiillerich et al., Vol. 56, pp. 25-30 (1995).
	*	"Prevention of upper gastrointestinal bleeding in long term ventilated patients" by Laggner et al., <u>Am. J. Med.</u> , Vol. 86, Suppl. 6A, pp. 81-84 (1989).
	*	"Gastric response to severe head injury" by Larson et al., <u>Am. J. Surg.</u> , Vol. 147, pp. 97-105 (1984).
	*	"Pathogenesis, diagnosis and treatment of acute gastric mucosa lesions" by Marrone & Silen, <u>Clin. Gastroenterol.</u> , Vol. 13, pp. 635-50 (1984).
	*	"Continuous intravenous cimetidine decreases stress-related upper gastrointestinal hemorrhage" by Martin, et al., <u>Crit. Care Med.</u> , Vol. 21, pp. 19-39 (1993).
	*	"Evaluation of various techniques to monitor intragastric pH" by Meiners et al., <u>Arch. Surg.</u> , Vol. 117, pp. 288-91 (1982)
	*	"Electrolyte and acid-base disorders" by Oh & Carroll, <u>The Pharmacologic Approach to the Critically Ill Patient</u> , pp. 966-67 (Chernow, B. ed. 1994).
	*	"Control of gastric pH with cimetidine boluses versus primed infusions" by Ostro et al., <u>Gastroenterology</u> , Vol. 89, pp. 532-37 (1985).
	*	"Cimetidine for prevention and treatment of gastroduodenal mucosal lesions in patients" by Peura & Johnson, <u>Ann. Intern. Med.</u> , Vol. 103, pp. 173-177 (1985).
	*	"Occurrence of nasocomial pneumonia in mechanically ventilated trauma patients" by Pickworth, et al., <u>Crit. Care Med.</u> , Vol. 12, pp. 1856-62 (1993).
	*	"Methods of prophylaxis in stress ulcer disease" by Priebe & Skillman, <u>World J. Surg.</u> , Vol. 5, pp. 223-33 (1981).

EXAMINER

DATE CONSIDERED

EXAMINER: Initial citation considered. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

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## OTHER DOCUMENTS (Including Author, Title, Date, Place of Publication)

	*	"Nasocomial pneumonia during stress ulcer prophylaxis with cimetidine and sucralfate" by Ryan et al., <u>Arch. Surg.</u> , Vol. 128, pp. 1353-57 (1993).
	*	"Clinically important adverse effects and drug interactions with H2-receptor antagonists: an update" by Sax, <u>Pharmacotherapy</u> , Vol. 7, pp. 110S-115S (1987).
	*	"Stress ulcer prophylaxis: still a valid option in the 1990s?" by Schepp, Vol. 54, pp. 189-99 (1993).
	*	"Prophylactic therapy for acute ulcer bleeding: a reappraisal" by Schuman et al., <u>Ann. Intern. Med.</u> , Vol. 106, pp. 562-67 (1987).
	*	"Stress ulcer prophylaxis: in whom? with what?" by Schuster, <u>Crit. Care Med.</u> , Vol. 21, pp. 4-6 (1993).
	*	"A dosage alternative for H-2 receptor antagonists, continuous-infusion" by Siepler, <u>Clin. Ther.</u> , Vol. 8, pp. 24-33 (1986).
	*	"Role of gastric colonization in the development of pneumonia in critically ill trauma patients" by Simms et al., <u>J. Trauma</u> , Vol. 31, pp. 531-36 (1991).
	*	"Respiratory failure, hypotension, sepsis and jaundice: a clinical syndrome associated with lethal..." by Skillman et al., <u>Am. J. Surg.</u> , Vol. 117, pp. 523-30 (1969).
	*	"The gastric mucosal barrier: clinical and experimental studies in critically ill and normal man..." by Skillman et al., <u>Ann. Surg.</u> , Vol. 172, pp. 564-84 (1970).
	*	"Changing perspectives of stress gastritis prophylaxis" by Smythe & Zarowitz, <u>Ann. Pharmacother.</u> , Vol. 28, pp. 1073-84 (1994).
	*	"Thrombocytopenia associated with ranitidine" by Spychal & Wickman, <u>Br. Med. J.</u> , Vol. 291, p. 1687 (1985).
	*	"Stress ulcer prophylaxis - quo vadis?" by Tryba, <u>Intens. Care Med.</u> , Vol. 20, pp. 311-13 (1994).
	*	"Risk of acute stress bleeding and nosocomial pneumonia in ventilated intensive care patients. Sucralfate vs. antacids" by Tryba, <u>Am. J. Med.</u> , Vol. 87 (3B) 117-24 (1987).
	*	"Side effects of ranitidine" by Vial et al., <u>Drug Saf.</u> , Vol. 6, pp. 94-117 (1991).
	*	"The relationship between gastric acid secretion and gastric H <sup>+</sup> /K <sup>+</sup> -ATPase activity" by Wallmark et al., <u>J. Biol. Chem.</u> , Vol. 260, pp. 13681-84 (1985).
	*	"Tolerance during dosing with H2 receptor antagonists: An overview" by Wilder-Smith & Merki, <u>Scand. J. Gastroenterol.</u> , Vol. 27, Suppl. 193, pp. 14-19 (1992).
	*	"The prevention of gastro-intestinal tract bleeding in patients in an intensive care unit" by Zinner et al., <u>Surg. Gynecol. Obstet.</u> , Vol. 153, pp. 214-20 (1981).
	*	"Influence of insulin antibodies on pharmacokinetics and bioavailability of recombinant human..." by Gray et al., <u>British Med. J.</u> , Vol. 290, pp. 1687-90 (1985).
		"Nasogastric Administration of Omeprazole for Control of Gastric pH" by Carroll, et. al., <u>10<sup>th</sup> World Congresses of Gastroenterology</u> , Abstracts (October 2-7, 1994).
	*	"A Lansoprazole suspension Formulation as an Alternative to Capsules for Oral Administration" by SP Lockhart & G. Baxter, <u>World Congresses of Gastroenterology</u> , Abstracts (Sept. 6-11, 1998).

EXAMINER

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## OTHER DOCUMENTS (Including Author, Title, Date, Place of Publication)

		"Gastric acid antisecretory effect of two different dosage forms of omeprazole during prolonged oral treatment in the gastric fistula dog" by Larsson et. al., Vol. 23, No. 8, pp. 1013-19 (1988).
		"Effect of various salts on the stability of lansoprazole, omeprazole, and pantoprazole as determined by high-performance liquid chromatography" by Ekpe, et al, <u>Drug Dev. Ind. Pharm.</u> , Vol. 25, No. 9, pp. 1057-65 (1999).
		"Inhibition of gastric secretion by omeprazole and efficacy of calcuim carbonate in the control of hyperphosphatemia in patients on maintenance hemodialysis" bu Sechet, et al., <u>Nephrologie</u> , Vol. 20, No. 4, pp. 213-16 (1999).
		"Role of the time of administration of calcium carbonate in the control of hyperphosphatemia in patients on maintenance hemodialysis" by Sechet, et al., <u>Nephrologie</u> , Vol. 20, No. 4, pp. 209-12 (1999).
		Onset of action of antisecretory drugs: beneficial effects of a rapid increase in intragastric pH in acid reflux disease" by Pipkin, et al, <u>Scand. J. Gastroenterol. Supp.</u> , Vol. 230, pp. 3-8 (1999).
		"Omeprazole Disposition in Humans" by Regardh, et al., <u>Ther. Drug Monit.</u> , Vol. 12, No. 2, pp. 165 (1990).
		"Evaluation of Buffering Capacity and Acid Neutralizing pH Time Profile of Antacids" by Lin, et al., <u>J Formos Med Assoc</u> , 1998, Vol. 97, No. 10, pp. 704-710.
		"A Study of Antacid Buffers: I. The Time Factor in Neutralization of Gastric Acidity", by Holbert, et al., <u>J. Am Pham Assoc, Sci Ed</u> , Vol. 36, 1947, pp. 149-151.
		"Buffered and Isotonic Solutions", <u>Physical Pharmacy</u> , Chapter 8, pp. 169-189
	*	"Influence of insulin antibodies on pharmacokinetics and bioavailability of recombinant human..." by Gray et al., <u>British Medical Journal</u> , 290: 1687-1690 (1985).
	*	"Inhibition of basal and betazole - and sham-feeding-induced acid secretion by omeprozole in man" by Lind, et al., <u>Scand. J. Gastroenterol</u> , 21:1004-1010 (1986).
	*	"Lansoprazole: Phase I Study of Lansoprazole (AG-1749) antiulcer agent" abstract in English; text in Japanese, by Nakagawa et al, (1991).
		"Pantopprozole Bicarbonate Suspension (PBS) Provides Oral Bioavailability Comparable to Tablet" by J. Paul, et al., <u>Critical Care Medicine</u> , Feb. 2001.
		<u>Physical Pharmacy - Physical Chemicals Principles in the Pharmaceutical Sciences</u> , Fourth Edition, by A. Martin, et al., 1993.

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